

# Human Dural Homografts

## Freeze-Dried Human Dura Mater for Closure of Dural Defects

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AN INDICATION of the importance placed on the closing of dural defects which occur with craniocerebral trauma, neoplasms or congenital defects is the number of materials which neurosurgeons have used as dural substitutes in recent years. While the British place less emphasis upon closing the dura, American surgeons make every effort to reduce the complications which may follow an open dura—cortical adhesions and cerebral seizures, cerebrospinal fluid fistula, cerebral fungus formation, failure of later cranioplasty due to cerebrospinal fluid fistula or infection.

Among the substances used to replace dura mater have been autogenous transplants of fascia lata, dura mater, pericranium, temporal fascia, muscle and fat.

Various metals have been tried, among them gold, platinum, silver, aluminum, nickel, stainless steel and tantalum.

Softer materials have been inserted in place of dura—rubber sheet, parchment, gutta-percha, celluloid, cellophane, human amniotic membrane, amnioplastin, beef allantoinic membrane, and Cargile membrane.

Recently plastic materials have been used, the list including polyvinyl alcohol film, fibrin film, gel-foam film, polyethylene film, gelatine film, orlon and vinyon "N."

Because each dural substitute has had some disadvantage, either theoretical or practical, search for the ideal substance continues. This report of the use of human freeze-dried dura for closing dural defects is not intended to claim the superiority for it over other materials, but to point up its availability and to record the successful use of preserved human dura mater, in agreement with the reports of Sharkey and Campbell.

Dura has been among the last of the banked tissues to be tried for surgical replacement procedures. Various methods for preserving it have been tried, ranging from freeze-drying in extreme degrees of

• Freeze-dried human dura mater homograft has proved a highly successful, readily available and conveniently stored material for closure of dural defects.

The material was used in three patients with good results as appraised after observation for periods of from two months to two years after operation.

The freeze-dried dural homograft offers certain advantages over plastic implants, with regard to tissue acceptance by the host and more physiologic tissue response.

cold<sup>3</sup> to sterilization by exposure to ethylene oxide<sup>5</sup> and beta-propiolactone.<sup>6</sup> Bone, cartilage, artery, cornea, and skin have all been used. Each tissue, being a free graft, serves primarily as a matrix for fibroblastic activity. In the case of arterial homografts, the grafts remain in place even after four years, and on examination it has been found that fibrous tissue from the host has covered the graft on both sides.

The dural homograft has been studied microscopically after placement.<sup>5</sup> It too is partially replaced by fibrous tissue from the host. It is increased in thickness two or three times, but still is quite pliable and soft in texture. There is no evidence of foreign body reaction or excessive scar formation. From these observations, it is assumed that the dural homografts are gradually replaced by fibrous tissue. The dead dural graft remains intact during the slow process of replacement.

Sterility of the grafts has been assured by repeated cultures. However, the use of antibiotics after the placement of freeze-dried dura is advisable, since it may be considered a foreign material.

### MATERIALS AND METHODS

The freeze-dried dura mater used in these cases was made available through the kindness of Captain George W. Hyatt, M.C., U.S.N., who, with his associates at the Tissue Bank of the U. S. Naval Medical School, Bethesda, Maryland, tested its efficacy in animal experimentation<sup>4</sup> and certified its sterility after cultures.

The dura mater as produced by the Tissue Bank became available after a technique of freeze-drying for processing and storage of dura mater and other

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tissues was perfected. The tissues are obtained from acceptable cadavers.<sup>3</sup> The dura mater is removed under aseptic conditions and rapidly frozen at temperatures ranging from  $-78^{\circ}$  C. to  $-196^{\circ}$  C. While still frozen, the tissues are placed in a vacuum chamber until dried by sublimation and then stored in vacuum sealed bottles.

Tissues preserved in this manner may be stored for years at room temperatures as long as the vacuum is maintained. When a freeze-dried tissue is immersed in warm sterile normal saline solution for 10 minutes, it quickly regains pliability to permit surgical handling. The reconstituted dura mater has a tensile strength about that of fresh dura mater.

Lyophilized dura mater as prepared by Sharkey is obtained at autopsy, sterilized by immersion in ethylene oxide, then freeze-dried. The finished product is packaged in Pyrex glass tubes, sealed in an atmosphere of nitrogen. It is soaked in warm normal saline solution for 10 minutes to make it ready for use.

#### REPORTS OF CASES

The cases reported here vividly illustrate some of the complications which occur when the dura mater is not carefully closed at the time of primary handling of the craniocerebral injuries. They also point up the importance of keeping on hand some form of dural substitute in hospitals that deal with severely injured patients. Fortunately, there is now available lyophilized human dura from a commercial source\* and freeze-dried dura mater from the U. S. Naval Medical School Tissue Bank, Bethesda.<sup>†</sup>

**CASE 1.** The patient, a 28-year-old, right-handed woman, was admitted in emergency to Memorial Hospital of Glendale on February 17, 1959, following a gunshot wound with a 38-caliber bullet at very close range, the bullet passing through the right posterior parietal area.

The patient was semi-comatose, crying loudly, disoriented and unaware of surroundings. Right peripheral facial paralysis, left hemiparesis and positive Babinski sign on the left were noted, with deafness to loud noises on the right. Roentgen examinations of the skull revealed a 38-caliber bullet lodged in the middle fossa and fracture of the petrous ridge on the right.

Right temporal osteoplastic craniotomy was carried out, with debridement of scalp, temporal bone, dura and brain, partial temporal lobectomy and removal of the bullet.

The patient made a good recovery, but right cerebral spinal fluid otorrhea developed due to a dural tear in the floor of the middle fossa and frac-

ture of the petrous ridge which could not be repaired at the time of the original operation.

On March 6, 1959, freeze-dried dura having been obtained, closure of the dural defect in the right middle fossa over the petrous ridge of the temporal bone was performed with a homograft of the substitute material. The fracture site was first sealed with bone wax and gelfoam, after which complete closure of the dural defect was made with freeze-dried dural homograft measuring 1.5 centimeters by 3 centimeters. A second dural flap measuring 3 centimeters by 8 centimeters was placed over a lateral tear in the dura to make a water-tight closure over the defect made by penetration of the bullet.

The patient made excellent recovery and the cerebral spinal fluid otorrhea ceased. Neurological examination revealed complete nerve deafness of the right ear, complete peripheral facial palsy, hypesthesia over the second and third divisions of the trigeminal nerve on the right, left hemiparesis and slight spasticity and incoordination of movements of the left hand as compared with the right.

Because of the peripheral facial paralysis and the partial involvement of the fifth cranial nerve as well, a right spinofacial anastomosis was performed March 13 to compensate for the complete severance of the seventh cranial nerve in the petrous portion of the temporal bone. The spinal accessory nerve was selected in view of the fact that the patient had an existing fifth and seventh nerve involvement. To add a hypoglossal palsy on the same side would have meant considerable drooling. For this reason, the eleventh cranial nerve was selected.

The patient was discharged one week following this last procedure. After six months she was walking and speaking normally, facial asymmetry was improving a little and some beginning of facial movements was noted.

A year after the operation the patient had excellent tonus of the left side of the face at rest. There was still asymmetry, but she had some voluntary movements of the face and the eye on attempted movement of the right shoulder. Meantime the patient had had a successful pregnancy and delivery.

On February 17, 1961, two years after the gunshot wound and the placement of freeze-dried dural homograft from the U. S. Navy Tissue Bank, the patient was doing exceptionally well. There was no reaction; she had had no cerebral seizures, and except for minor headaches was carrying on her normal activity as a mother.

**CASE 2.** The patient, a 17-year-old, right-handed boy, had a gunshot wound of the head, the bullet entering the left frontal area, going through the frontal cranium into the parietal area and a fragment lodging in the occipital lobe on the left side.

\*Taylor Laboratories, Inc., Houston, Texas.

†U. S. Naval Medical School Tissue Bank, Bethesda, Maryland.

The patient was immediately admitted to hospital and incomplete debridement of the scalp, cranium, dura and brain was performed. No attempt was made to debride the brain or to remove the bullet for fear of increasing the extent of tissue damage. The brain was merely covered with gelfoam and a large dural defect was still present. The scalp was closed with wire over a large cranial opening.

Ten days later the patient was transferred to the Memorial Hospital of Glendale. A cerebrospinal fluid fistula had developed through the scalp incision in the area of the bullet entrance. The patient's temperature was spiking to 102° to 103° F. daily. He was still aphasic, had right hemiparesis and right parietal lobe deficit with hemihypesthesia. Purulent material was draining from the scalp flap incision and there was a bulging fluctuant area beneath the flap.

On May 10, following intensive antibiotic therapy, a left frontotemporal scalp flap was reopened and early abscess formation was noted in a cerebral fungus that was mushrooming through a 2 cm. dural defect in the left posterior frontoparietal area. Careful debridement of brain and excision of cerebral fungus was then carried out. The dural edges were debrided and a homograft of freeze-dried dura was then placed in the large dural defect, the patch being 4x9 cm. A water-tight closure was obtained.

The patient did exceptionally well postoperatively except for one or two galeal sutures which became infected and had to be removed.

On December 16, 1960, left frontoparietal acrylic cranioplasty was performed to fill a cranial defect. At the time of operation, the dural graft was inspected and was found to be well healed with no reaction, and the pericranium was dissected from it with ease. The cranial defect edges were easily freed from the dura, and it was noted that the dural graft blended imperceptibly with the normal dura, even the sutures being almost undetectable. The graft appeared to be about twice the thickness of normal dura.

The patient recovered from the cranioplastic procedure without incident and was discharged five days later. His neurologic deficit was remarkably small in view of the large amount of cerebral fungus which had to be removed at the time of the original operation. When last observed he had slight parietal lobe findings of the right hand with some astereognosis, otherwise had normal strength and speech and was carrying on normal activity at school for his age and grade.

**CASE 3.** The patient was a 17-year-old, right-handed boy who in an automobile collision received lacerations of the face and a depressed frontal skull fracture with avulsion of scalp and bone. He was

taken immediately to an emergency hospital where a general surgeon who examined him noted he was comatose, that the pupils were widely dilated and fixed and that there was profuse bleeding from a large frontal scalp laceration and depressed skull fracture. As he was in considerable respiratory distress, tracheotomy was performed in the emergency room and meanwhile burr holes were made through transverse temporal incisions that were 1 cm. above the ear and 8 centimeters in length. The laceration of the scalp was then closed over a large dural defect without debridement of brain, dura, or underlying galeal tissues. Although still comatose after these procedures were completed, the patient was moving all extremities well and the pupils had become normal in size.

Upon neurological consultation 24 hours postoperatively the patient was observed to have blood pressure of 130/70 mm. of mercury, a pulse rate of 84, a 12-centimeter transverse laceration across the forehead and considerable nuchal rigidity. The pupils were small (2 mm.) but equal and the disc margins were sharp with no hemorrhage. The patient was moving all extremities and both sides of the face on deep pain and the reflexes were hyperactive, more so on the left, with unsustained patellar clonus on the right. Babinski's sign was positive on both sides.

X-ray studies of the skull, cervical spine and rib cage were then taken and were negative for any fractures except for the depressed skull fracture. The patient was then transferred to the Glendale Sanitarium and Hospital.

After antibiotic therapy and allowing time for the condition of the patient to stabilize, a sample of human freeze-dried dura was obtained from the U. S. Naval Medical Center Tissue Bank, Bethesda.

On December 28, 1960, a bilateral carotid angiogram showed slight shift of the anterior cerebral artery from left to right, indicative of either cerebral edema or intracerebral hematoma of the right frontal pole.

Cranial exploration through the previously made scar was carried out. The frontal scalp and galea were debrided and the depressed skull fragments were removed. Under the depressed area a 2 cm. bulb of macerated and necrotic brain from the tip of the left frontal lobe was herniated through a hole in the dura 2 cm. in diameter. The brain was carefully debrided and all necrotic tissue removed down to normal brain tissue, the tip of the left frontal lobe being sacrificed.

The dural defect was then closed with freeze-dried human dura. This material was overlapped across the sagittal sinus, in which there was a small defect that had to be sutured. The posterior wall of the frontal sinus was completely fractured and curettage

of all the frontal sinus membranes was then carried out. Tubes were placed to drain the wound.

The patient did well postoperatively, becoming more alert, but elevation of temperature 100° to 101° F. continued and on the tenth postoperative day fluctuation was noted beneath the scalp flap. *Staphylococcus aureus*, coagulation-positive, sensitive to chloromycetin, grew on a culture of material aspirated from the fluctuating area. Appropriate antibiotic administration was carried out, further debridement was performed and an epidural abscess was drained. The patient then recovered without incident and with no elevation of temperature. His sensorium improved and the ability to talk returned. Three weeks later, the tracheotomy was closed and the patient was moving all extremities well, was talking coherently and rationally, was walking and had essentially no neurological abnormalities, although pulsation could be seen in the depression at the site of craniectomy. On February 5, 1961, he was discharged to his home with a proposal for acrylic cranioplasty some six months later. When last observed the patient had had no cerebral seizures and was doing well at home.

#### DISCUSSION

Dura mater homografts may be useful in such conditions as: Dural defects following craniocerebral trauma; closure of cerebrospinal fluid fistulas; defects following removal of tumors; closure of pericranial or temporal fascial defects; closure of dura mater in posterior fossa explorations; repair of congenital dural defects.

While pericranium is a readily available tissue and serves well as a dural substitute (as advocated by Hayes<sup>2</sup>) autografts of tensor fascia lata are often

difficult to use in a severely injured patient whose lower extremities may be so damaged that sterile removal of tissue cannot be done.

The closure of a dural defect by some means should be performed promptly, if post-traumatic epilepsy is to be reduced to a minimum.<sup>1,7</sup>

In the three cases presented, the material used to close the defects in the dura mater proved highly successful in potentially contaminated wounds, cerebrospinal fluid fistulae were checked. Although infection occurred in two wounds, the dura remained intact and prevented subdural empyema. In each instance, water-tight closures were achieved. All patients were improved and in two cases the dural homograft was undoubtedly life-saving.

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#### REFERENCES

1. Carrington, K. W., Taren, J. A., and Kahn, E. A.: Primary repair of compound skull fractures in children, *Surg. Gyn. & Obst.*, 110:203-209, Feb. 1960.
2. Hayes, Col. G. J.: Personal communication.
3. Hyatt, G. W., Turner, T. C., Bassett, C. A. L., Pate, J. W., and Sawyer, P. N.: New methods for preserving bone, skin and blood vessels, *Postgrad. Med.*, 12:239-254, 1952.
4. Sewell, W. H., Koth, D. R., Pate, J. W., and Bedell, W. C.: The present status of our experiments with freeze-dried grafts, *Nav. med. Res. Inst.*, Research report project No. NM 007 081.10.14, 13:291-304, 1955.
5. Sharkey, P. C., Usher, F. C., Robertson, R. C. L., Polard, C., Jr.: Lyophilized human dura mater as a dural substitute, *J. Neurosurg.*, 15:192-198, 1958.
6. Szilagyi, D. E., Overhulse, P. R., Shonnard, C. P., and Lo Grippo, G. A.: The sterilization of human arterial homografts with beta-propiolactone; experimental and clinical observations, *Surgical forum, Amer. Coll. Surg.*, 5:244-252, 1955.
7. Walker, A. E.: *Post-traumatic Epilepsy*, Charles C. Thomas, Springfield, Ill., 1949.

